

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of
Fedde, et al.

Serial No. 10/682,527

Filed: October 9, 2003



Attorney Docket No. 3417/03

Group Art Unit: Unknown

Examiner: Unknown

For METHODS FOR THE TREATMENT OR PROPHYLAXIS OF ALDOSTERONE-MEDIATED PATHOGENIC EFFECTS IN A SUBJECT USING AN EPOXY-STERIODAL ALDOSTERONE ANTAGONIST

January 16, 2004

Commissioner of Patents
PO Box 1450
Alexandria, VA 22313

SIR:

INFORMATION DISCLOSURE STATEMENT

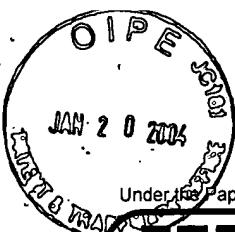
In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicants submit herewith various documents cited on the attached Form PTO 1449. Applicants respectfully request that the Examiner consider and enter all the documents cited on the enclosed Form PTO 1449 into the file of the above-identified application. Applicants also request an indication of the same by return of the Form PTO 1449 being initialed and dated by the Examiner.

Please charge the fee of \$180.00 as required by 37 C.F.R. § 1.17(p) to Deposit Account No. 19-1025. No additional fees are believed due to ensure consideration of the attached documents by the Examiner. However, if any additional fees are required or an overpayment of fees made, the Commissioner is hereby authorized to debit or credit our Deposit Account No. 19-1025, as necessary.

Respectfully submitted,

Joseph R. Schuh, Reg. No. 48,180
Agent for Applicants
(314) 274-8182 (St. Louis)

Pharmacia Corporation
Corporate Patent Department
P.O. Box 1027
Chesterfield, MO 63006



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27	
TOTAL AMOUNT OF PAYMENT	(\\$) \$180.00

Complete if Known

Application Number	10/682,527
Filing Date	October 9, 2003
First Named Inventor	Fedde et al
Examiner Name	Unknown
Group Art Unit	Unknown
Attorney Docket No.	S0-3417/3

METHOD OF PAYMENT (check all that apply)

<input type="checkbox"/> Check	<input type="checkbox"/> Credit card	<input type="checkbox"/> Money Order	<input type="checkbox"/> Other	<input type="checkbox"/> None
<input checked="" type="checkbox"/> Deposit Account:				

Deposit Account Number	19-1025
Deposit Account Name	Pharmacia Corporation

The Commissioner is authorized to: (check all that apply)

<input checked="" type="checkbox"/> Charge fee(s) indicated below	<input checked="" type="checkbox"/> Credit any overpayments
<input checked="" type="checkbox"/> Charge any additional fee(s) during the pendency of this application	
<input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.	

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity	Small Entity	Fee Description	Fee Paid	
Fee Code	Fee Code	Fee (\$)	Fee (\$)	
1051	2051	130	65	Surcharge - late filing fee or oath
1052	2052	50	25	Surcharge - late provisional filing fee or cover sheet
1053	1053	130	130	Non - English specification
1812	1812	2,520	2,520	For filing a request for ex parte reexamination
1804	1804	920*	920*	Requesting publication of SIR prior to Examiner action
1805	1805	1,840*	1,840*	Requesting publication of SIR after Examiner action
1251	2251	110	55	Extension for reply within first month
1252	2252	410	205	Extension for reply within second month
1253	2253	930	465	Extension for reply within third month
1254	2254	1,450	725	Extension for reply within fourth month
1255	2255	1,970	985	Extension for reply within fifth month
1401	2401	320	160	Notice of Appeal
1402	2402	320	160	Filing a brief in support of an appeal
1403	2403	280	140	Request for oral hearing
1451	1451	1,510	1,510	Petition to institute a public use proceeding
1452	2452	110	55	Petition to revive - unavoidable
1453	2453	1,300	650	Petition to revive - unintentional
1501	2501	1,300	650	Utility issue fee (or reissue)
1502	2502	470	235	Design issue fee
1503	2503	630	315	Plant issue fee
1460	1460	130	130	Petitions to the Commissioner
1807	1807	50	50	Processing fee under 37 CFR § 1.17(q)
1806	1806	180	180	Submission of Information Disclosure Statement
8021	8021	40	40	Recording each patent assignment per property (times number of properties)
1809	2809	750	375	Filing a submission after final rejection (37 CFR § 1.129(a))
1810	2810	750	375	For each additional invention to be examined (37 CFR § 1.129(b))
1801	2801	750	375	Request for Continued Examination (RCE)
1802	1802	900	900	Request for expedited examination of a design application
Other fee (specify) _____				

FEE CALCULATION**1. BASIC FILING FEE**

Large Entity	Small Entity			
Fee Code	Fee Code	Fee (\$)	Fee Description	Fee Paid
1001	2001	750	375	Utility filing fee
1002	2002	330	165	Design filing
1003	2003	520	260	Plant filing fee
1004	2004	750	375	Reissue filing
1005	2005	160	80	Provisional filing fee
SUBTOTAL (1) (\$)				

2. EXTRA CLAIM FEES FOR UTILITY AND

	Extra Claims	Fee from below	Fee Paid
Total Claims	-20** =	0	X _____ = 0.00
Independent Claims	-3** =	0	X _____ = 0.00
Multiple Dependent			= _____

Large Entity	Small Entity	Fee Description		
Fee Code	Fee Code	Fee (\$)		
1202	2202	18	9	Claims in excess of 20
1201	2201	84	42	Independent claims in excess of 3
1203	2203	280	140	Multiple dependent claim, if not paid
1204	2204	84	42	** Reissue independent claims over original patent
1205	2205	18	9	** Reissue claims in excess of 20 and over original patent
SUBTOTAL (2) (\$)				

**or number previously paid, if greater; For Reissues, see above

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3) (\$)**

\$180.00

SUBMITTED BY**Complete (if applicable)**

Name (Print/Type)	Joseph R. Schuh	Registration No. (Attorney/Agent)	48,180	Telephone	314-274-8182
Signature	<i>Joseph R. Schuh</i>			Date	1/16/04

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: S03417/03	APPLICATION NO.: 10/682,527	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		INVENTOR: Fedde, et al.				
		(Use several sheets if necessary)		Filed: 10/9/03	Group:	

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
1	4559332	12/17/1985	Grob et al.	514	175	09 APR 1984
2	5145684	09/08/1992	Liversidge et al.	424	489	25 JAN 1991
3	5318767	06/07/1994	Liversidge et al.	424	4	10 AUG 1992
4	5384124	01/24/1995	Courteille et al.	424	430	12 FEB 1992
5	5747001	05/05/1998	Wiedmann et al.	424	45	24 FEB 1995

FOREIGN PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
6	WO9721720	✓ 19.06.97	US	C07J	21/00	X	
7	WO9825948	✓ 18.06.98	US	C07J		X	
8	WO9640257	✓ 19.12.96	US	A61K	45/06	X	
9	EP0122232	✓ 10.04.84	Europe	C07J	71/00		X
10	WO0027380	✓ 18.05.00	US	A61K	31/00	X	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Examiner Initial		
	11 ✓	Funder, John W., <i>Current Opinion in Endocrinology and Diabetes</i> , 7(3): 138-142, 2000
	12 ✓	Epstein, M., et al., <i>Journal of the American Society of Nephrology</i> , Vol. 9, 322A-323A, September 1998
	13 ✓	Luft, FC, <i>Wiener Klinische Wochenschrift</i> , 110/13-14: 459-566, 31 July 1998
	14 ✓	Rabasseda, X., et al., <i>Drugs of the Future</i> , Volume 24, (5) : 488-501, 1999
	15 ✓	Ichikawa, S., et al., <i>Japanese Circulation Journal</i> , 48(11): 1184-1196, 1984
	16 ✓	Blumenfield and Laragh, <i>Congestive Heart Failure Pathophysiology, Diagnosis & Management</i> , 1 st edition, Caddo (OK), Professional Communications, Inc., 1994
	17 ✓	MacMahon, S., et al., <i>Lancet</i> , 335:765-774, 1990
	18 ✓	United States Renal Data System 1999 Annual Data Report, <i>American Journal of Kidney Disease</i> , 34, Suppl 1: S1-S176, 1999
	19	Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, <i>Arch Internal Medicine</i> , 157: 2413-2446, 1997
	20	Dzau, VJ, et al., <i>Circulation</i> , 63:645-651, 1981
	21	Gerber, JG, et al., "Antihypertensive Agents & Drug Therapy of Hypertension" from <i>Goodman & Gilman's The Pharmacological Basis of Therapeutics</i> , 8 th edition, New York: McGraw-Hill, pp 784-813, 1993
	22	Weber, KT, et al., <i>Circulation</i> , 75(Suppl I): I40-I47, 1987
	23	Struthers, AD, <i>Journal of Cardiac Failure</i> , 2(1): 47-54, 1996
	24	Rocha, R., et al., <i>American Journal of Hypertension</i> , 12: 76A, 1999
	25	Staessen, J., et al., <i>Journal of Endocrinology</i> , 91: 457-465, 1981
	26	Pitt, B., <i>Cardiovascular Drugs and Therapy</i> , 9: 145-149, 1995
	27	Marayev, V., et al., <i>Presentation at the International Meeting on Heart Failure</i> , 1995, Amsterdam, The Netherlands

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: S03417/3	APPLICATION NO.: 10/682,527
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		INVENTOR: Fedde, et al.	
(Use several sheets if necessary)		Filed: 10/9/03	Group:

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Examiner Initial		
28	Greene, E., et al., <i>Journal of Clinical Investigation</i> , 98: 1063-1068, 1996	
29	Hené, RJ, et al., <i>Kidney International</i> , 21: 98-101, 1982	
30	Berl, T., et al., <i>Kidney International</i> , 14: 228-235, 1978	
31	Ibrahim, HN, et al., <i>Seminars in Nephrology</i> , 17: 431-440, 1997	
32	Quan, ZY, et al., <i>Kidney International</i> , 41: 326-333, 1992	
33	Gavras, H., et al., <i>Circulation Research</i> , 36: 300-309, 1975	
34	Horiuchi, M., et al., <i>American Journal of Physiology</i> , 264 (2 Part 2) F: 286-291, 1993	
35	Ullian, ME, et al., <i>American Journal of Physiology</i> , 272 (3 Part 2) H: 1454-1461, 1997	
36	Hansson, L., et al., <i>Lancet</i> , 351: 1755-1762, 1988	
37	Joint National Committee, The 6 th Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, <i>NIH Publication Number 98-4080</i> , November 1997	
38	Kaplan, NM, <i>Journal of Hypertension</i> , 13 (Suppl 2): S113-S117, 1995	
39	Swedberg, K., et al., <i>Circulation</i> , 82: 1730-1736, 1990	
40	AIRE Study Group, <i>Lancet</i> , 342: 821-828, 1993	
41	Pitt, B., et al., <i>The New England Journal of Medicine</i> , 341 (10): 709-717, 1999	
42	The RALES Investigators, <i>American Journal of Cardiology</i> , 78: 902-912, 1996	
43	Kannel, WB, et al., <i>American Heart Journal</i> , 108: 1347-1352, 1984	
44	Maki, DD, et al., <i>Arch Internal Medicine</i> , 155: 1073-1082, 1995	
45	Heeg, JE, et al., <i>Kidney International</i> , 36: 272-280, 1989	
46	MacGregor, GA, et al., <i>Experiments in Hypertension</i> , 5: 1367-1380, 1983	
47	Buter, H., et al., <i>Nephrology Dial Transplant</i> , 13: 1682-1685, 1998	
48	Weir, J., <i>Journal of Human Hypertension</i> , 11: 17-21, 1997	
49	Pratt, JH, et al., <i>Hypertension</i> , 34: 315-319m 1999	
50	<i>The Merck Manual</i> , 17 th edition, pp 1526-2528, 1999	
51	Ganong, WF, <i>Review of Medical Physiology</i> , 6 th edition, Lange Medical Publications, Los Altos, Calif.	
52	American Heart Association Nutrition Committee, "Dietary Guidelines for Healthy American Adults," <i>Circulation</i> , 77: 721-724, 1988	
53	NIH News Release: "NHLBI Study Shows Large Blood Pressure Benefit From Reduced Dietary Sodium," May 17, 2000	
54	Bakris, GL, et al., <i>American Journal of Hypertension</i> , 9: 200S-206S, 1996	
55	Campese, VM, <i>Hypertension</i> , 19: 403-418, 1992	
56	Neaton, JD, et al., <i>JAMA</i> , 270: 713-724, 1993	
57	Grim, CE, et al., <i>Journal of Chronic Disease</i> , 33: 87-94, 1980	
58	Van Brummelen, P., et al., <i>Acta Med Scand</i> , 204: 151-157, 1978	
59	Weinberger, MH, et al., <i>JAMA</i> , Volume 259 (17): 2561-2565, 1988	
60	Sullivan, JM, <i>Hypertension</i> , 17 (Suppl I): I61-I68, 1991	
61	Weir, MR, et al., <i>Hypertension</i> , 16: 235-244, 1990	

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: S03417/3	APPLICATION NO.: 10/682,527
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		INVENTOR: Fedde, et al.	
		Filed: 10/9/03	Group:

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Examiner Initial	
62	Brenner, K., <i>Current Opinions in Nephrology Hypertension</i> , 2(3): 341-349, May 1993
63	Grim, et al., <i>Hypertension</i> , 1476-485, 1979
64	Strazzullo, et al., <i>Journal of Nephrology</i> , 13: 46-53, 2000
65	Powers, DR, et al., <i>Archives of Internal Medicine</i> , 158: 793-800, 1998
66	Ruthledge et al., <i>Journal of Hypertension</i> , 13: 953-955, 1995
67	Svetkey, et al., <i>Hypertension</i> , 29: 918-922, 1997
68	Cusi, D., et al., <i>Lancet</i> , 349: 1353-1357, 1997
69	Lovati, E., et al., <i>Journal of Clinical Endocrinology and Metabolism</i> , 84: 3745-3749, 1999
70	Ferrari, P., et al., <i>Kidney International</i> , 57: 1374-1381, 2000
71	Giner, et al., <i>Hypertension</i> , 35: 512-517, 2000
72	Yanagiagwa, M., et al., <i>Nature</i> , 332: 411-415, 1988
73	De Nucci, G., et al., <i>Proceedings of the National Academy of Science, USA</i> , 85: 9797-9800, 1988
74	Schiffrin, EL, et al., <i>American Journal of Hypertension</i> , 4: 303-308, 1991
75	Eliovich, F., et al., <i>Hypertension</i> , 33: 1075, 1999
76	Saruta, T., <i>Journal of Clinical Therapeutic Medicine</i> , 13: 4024-4029, 1997
77	Shimamoto, K., <i>Japanese Cases, Nihon Rinsijo (Clinical Medicine in Japan)</i> , 58: 593-596, 2000
78	Nakagawa, H., et al., <i>Human Hypertension</i> , 13 (11): 735-741, November 1999
79	Kobayashi, Y., et al., <i>Japanese Circulation Journal</i> , 47 (2): 268-275, 1983
80	Guidelines on Treatment of Hypertension in Elderly, 1995, <i>Comprehensive Research Projects on Aging and Health, the Ministry of Health and Welfare of Japan</i>
81	Ogihara, T., et al., <i>Nippon Ronen Igakkai Zasshi</i> , 33 (12): 945-975, 1996
82	Mizushima, S., <i>Clinical Experiments in Pharmacology and Physiology</i> , 26: 573, 1999
83	Svetkey, LP, et al., <i>Hypertension</i> , 28: 854-858, 1996
84	Eisner, GM, <i>American Journal of Kidney Disease</i> , 16 (4 Suppl 1): 35-40, 1990
85	Flack, JM, et al., <i>Journal of Association of the Academy of Minority Physicians</i> , 2: 143-150, 1991
86	Flack, JM, et al., <i>Hypertension</i> , 17 (1 Suppl): I115-I121, 1991
87	Ferri, et al., <i>Diabetes</i> , 48: 1623-1630, 1999
88	Di Genaro, C., et al., <i>Hypertension</i> , 35: 869-874, 2000
89	Bonner, <i>MMW Fortscher Medizin</i> , 14: 34-36, 1999
90	Dimsdale, et al., <i>American Journal of Hypertension</i> , 3: 429-435, 1990
91	Falkner, B., et al., <i>American Journal of Clinical Nutrition</i> , 65: 618S-621S, 1997
92	Rocchini, AP, et al., <i>American Journal of Medical Science</i> , 307 (Suppl 1): S75-S80, 1994
93	Weinberger, MH, Presentation at the 54 th Annual Conference of the American Heart Association's Council for High Blood Pressure Research, Washington, DC, 2000
94	Bonafede, et al., <i>Journal of American Chemical Society</i> , 117: 30, 1995
95	Uusimaa, et al., <i>International Journal of Cardiology</i> , 69: 5-14, 1999
96	Stanton, B., et al., <i>Journal of Clinical Investigation</i> , 75: 1317-1326, 1985

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: S03417/3	APPLICATION NO.: 10/682,527
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i>		INVENTOR: Fedde, et al.	
		Filed: 10/9/03	Group:

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Examiner Initial		
97	Hou, J., et al., <i>Journal of Clinical Investigation</i> , 96: 2469-2477, 1995	
98	Rocha, R., et al., <i>Hypertension</i> , 33: 232-237, 1999	
99	Young, M., et al., <i>American Journal of Physiology</i> , 269: E657-E662, 1995	
100	Okamoto, K., et al., <i>Circulation Research</i> , 34&35 (Suppl I): I143-I153	
101	Stier, CT, et al., <i>Hypertension</i> , 13: 115-121, 1989	
102	Stier, CT, et al., <i>Journal of Pharmacology and Exp. Therapeutics</i> , 260: 1410-1415, 1992	
103	Sokolo, M., et al., <i>American Heart Journal</i> , 37: 161, 1949	
104	Neaton, JD, et al., <i>JAMA</i> , 270 6, 713-724, August 11, 1993	

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

(Form PTO-1449)